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Title: Method of Grouping and Analyzing Clinical Risks, and System Therefor

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1. ☒ Enclosed is the above-mentioned new patent application. It includes 4 sheet(s) of drawings.
2. ☒ Enclosed is an UN-executed declaration or oath.
3. ☐ Enclosed is an application assignment to 3M Innovative Properties Company and a completed Assignment Recordation Cover Sheet.
4. ☐ Enclosed is a Certified Copy of Priority Document(s) _____, (if foreign priority is claimed).
5. ☐ Enclosed is _____.
6. ☒ The fee for filing the application is computed as follows:

Claims As Filed					
(1) For	(2) Number Filed	(3) Number Extra	(4) Rate	(5) Basic Fee	
Total Claims	31 -20 =	11	x \$18.	\$760.	\$198
Independent Claims	4 -3 =	1	x \$78.		\$78
Additional fee for filing one or more multiple dependent claims			\$260.		\$260
Total amount due →					\$1296

7. ☒ Please charge to Deposit Account 13-3723 any fees under 37 CFR 1.16 and 1.17 which may be required to file and during the entire pendency of this application. This authorization includes the fee for any extension of time under 37 CFR 1.136(a) that may be necessary. To the extent any such extension should become necessary it is hereby requested. A copy of this transmittal letter for fee processing is enclosed.
8. ☒ Enclosed is a return receipt postcard

Respectfully submitted

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Method of Grouping and Analyzing Clinical Risks, and System Therefor

Statement of Government Rights

5 This invention was made with United States Government support under Cooperative Agreement Award no. 70NANB5H1013 awarded by the National Institute of Standards and Technology. The United States Government has certain rights in the invention.

Background of the Invention

Technical Field

10 The present invention relates to risk/cost analysis tools for estimating future health care costs, and in particular to tools for retrospective review and profiling to create risk groups.

Description of the Related Art

15 Estimates of the anticipated health care requirements and costs for a group of patients may be used for a variety of purposes, most notably anticipating costs for insurance and other purposes related to the financing of health care. Estimates typically are made by analyzing the historical records of the members of the population for which the estimate is being made and extrapolating future health care requirements from clinical and other defined characteristics of the population. Systems for doing this are generally referred to as risk adjusters, since they categorize individuals based on their future risk for needing health care services. However, the risk adjusters to date have operated only at a high level, with the result that their efficacy and utility is limited.

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25 In early risk adjusters, weights were calculated for each of a set of diagnostic categories and/or cost groups using a linear regression model. Only a single category, the most expensive, is chosen to estimate an individual's future costs and all other diagnoses are ignored. While a single factor clearly is inadequate for individuals with multiple problems, an additive approach is occasionally used. Currently available products, such as Hierarchical Coexisting conditions (HCC), determine the weight given each disease group using a linear regression model which assigns a weight for each of a set of diagnostic categories. Then, where and when applicable, the weights for each diagnostic category in an individual's history are added to get a total weight. The total weight is converted into a

predicted cost for the next year. Additive approaches, however, may also not accurately represent the relationship between ostensibly independent problems. For example, consider the case of individuals with diabetes and hypertension, which generally are considered independent but interactive disease processes. While diabetes does not cause hypertension, or vice versa, it is not unusual for an individual to have both. However, the additional or marginal cost for treating a diabetic with hypertension may actually be considerably less than simply adding the cost for treating a non-hypertensive diabetic to the cost for treating a non-diabetic hypertensive. This makes intuitive sense when one considers that the diabetic already is making regular office visits for the diabetes, blood pressure is routinely checked during any medical office visit, so the costs are likely not equal to the costs of treating diabetes and hypertension independently.

Some past risk adjustment systems (e.g., the Medicare Diagnosis Related Groups, or DRGs) include some historical indication of overall severity at a particular time in a particular setting, but they do not explicitly identify severity by category of disease or project its likely impact upon medical needs into the future. The severity level of a disease can directly affect how that disease interacts with other diseases, and the consequent need for future care. To continue with the example just described, the example probably is true for low severity diabetes and low severity hypertension, but the opposite may be true for high severity diabetes and high severity hypertension. When both diseases are high severity, they can interact, making both diseases harder to treat. A system not explicitly incorporating severity into its logic will not identify this interaction risk.

Estimating costs using weights reflecting individuals from different points in the disease process also can be misleading. Individual health care needs vary not only by disease, but also by severity of disease. For example, at least in its early stages, hypertension is a relatively minor condition for many people, controllable by diet and exercise. However, for people in more advanced stages, it may be a fairly serious problem. It may require aggressive treatment, including occasional hospitalization, as well as posing a high risk of other significant cardiovascular problems. A single weight will not accurately reflect the severity of a disease experienced by individuals at different stages of the disease. No current risk adjustment system explicitly identifies levels of severity of disease.

Current systems also ignore the temporal aspects of care, such as treatment which may eliminate prior problems. For example, a patient with angina who undergoes a coronary arterial bypass graft (CABG) would not be expected to experience a recurrence of angina in the period following the bypass. But current systems do not take this into account – if angina has been recorded at any time, they continue to assume angina is present until such time as it no longer appears in the data.

The current systems, such as that in U.S. Patent 5,557,514, were designed to predict future costs to allow calculation of insurance rates and identification of providers with high utilization profiles, but are of limited value to in helping providers to actually control costs. The capitated payment arrangements typical of health maintenance organizations and preferred provider organizations place the majority of financial risk on the providers of care. The underlying assumption is that since providers are responsible for the delivery of care, they can respond to the incentives to control costs inherent in a capitated payment system.

The success of any payment system that is predicated on providing incentives for cost control is almost totally dependent on the effectiveness with which the incentives are communicated to providers. Payers need to express the payment arrangements in a form that communicates the incentives in the system in a manner and at a level of detail that promotes effective management responses.

But detailed clinical descriptions are not considered in current systems, and, more importantly, explicit severity levels and interactions among clinical conditions are not a part of a group assignment. Therefore, data from such systems is of limited value to clinicians, who need to understand the clinical basis of their costs in order to respond effectively to incentives inherent in capitated payment systems. While it sometimes is possible to use the information from such risks adjuster to identify where pro-active efforts could substantially reduce problems (and costs), it is very difficult.

Summary of the Invention

The present invention creates a comprehensive set of risk groups which in particular explicitly identifies groups of individuals with multiple interacting co-morbid conditions, and which explicitly identifies the severity of illness level. This allows accurate prediction of future health care resource needs of an entire population, while

simultaneously helping the health care provider isolate problems to identify changes in care to reduce costs and improve quality.

The present invention starts this process by developing a classification system that rates both the nature and severity of health care requirements, then applies that system to historical information for both individual patients and populations to group them according clinical risks. Each individual will fall into a single, mutually exclusive risk group in the classification system. Each risk group relates the historical clinical and demographic characteristics of the individual to the amount and type of health care resources that individual likely will consume in the future. Since the clinical risk groups are clinically based, they create a system that links the clinical and financial aspects of care. Thus, the clinical risk groups are designed to serve as the foundation of management systems which support care pathways, product line management and case management.

The present invention assumes there is at least one set of medical care codes available which is used to describe patient treatment. According to the present invention, the classification system is created by categorizing the medical care codes into major disease categories, and subdividing each major disease category into a plurality of episode disease categories based on the severity and/or longevity of the disease. The episode disease categories within each major disease category are ranked in seriousness, with, e.g., chronic diseases (e.g., emphysema) rated more severely than acute diseases which by their nature usually will last only a short while (e.g., pneumonia). In addition, severity of illness levels preferably are defined for episode disease categories.

In the typical situation, there in fact will be multiple sets of medical care codes, e.g., one used by hospitals and one used by physicians. Each of them can be categorized into its own sets of categories, though the level of detail applied may vary by set. For example, hospitals tend to have a far larger number of codes than physicians, so a more detailed categorization would be appropriate.

The classification system is applied to a set of historical data for an individual patient by first identifying all episode disease categories experienced by that individual. The episode disease categories within each major disease category are then adjusted to take into account to take into account the nature and timing of treatment events. For example, an individual with a history of angina, who then has angioplasty, can be expected to not have angina in the future. The episode disease category for angina therefore should

be deleted, unless the angina has recurred some significant period of time (e.g., 90 days) after the angioplasty. Note that the information from multiple sets of codes may interact in this adjustment (e.g., angina often will be identified from physician records, while angioplasty will normally be identified from hospital records). The severity of illness is adjusted in a similar manner.

Once the episode disease categories have been defined and severity of illness adjusted, the primary chronic disease is identified for each major disease category. The severity of illness for each major disease category typically will be the same as that for the primary chronic disease, but may need to be adjusted if there are episode disease categories in other major disease categories which interact with it, e.g., amputation of extremities implies that a patient with diabetes is in an extremely advanced state of diabetes, which may be even worse if the patient also has congestive heart failure.

The major disease categories and their respective severity of illnesses then are aggregated in a similar fashion to identify a single clinical risk group for the individual, and an overall severity of illness for the individual.

The classification system then also defines a method for aggregating information about groups of patients, to allow the summation of information about large numbers of patients. Preferably, this involves grouping the clinical risk groups into aggregated clinical risk groups at a variety of levels.

A significant advantage to the present invention is that it allows health care providers to identify and pro-actively treat health problems. Unlike present capitation rate calculation systems, the clinical risk groups developed and used according to the present invention directly communicate information in a form and at a level of details that can lead to specific positive actions. To illustrate the difference, suppose that for individuals with diabetes the capitated payments are 25% lower than the provider's expenditures. While this is obviously useful information for identifying a problem, it does not give the provider any real information on the precise source of the problem, or the actions that can be taken to correct the problem. In contrast, suppose the payment system also provided the following information:

"The higher costs for diabetic individuals are due to unusually high expenditures for inpatient care combined with uncommonly low expenditures for pharmacy and outpatient laboratory services for severity of illness level 1 and 2 diabetic

individuals. Further a higher than expected percentage of severity of illness level 1 and 2 diabetic individuals over time become severity level 3 or 4.”

Clearly, the above information raises specific questions concerning the monitoring and preventive care being provided to individuals with low severity diabetes, which gives providers a basis for management action, and an effective response to the incentives in the payment system.

Another significant advantage of the present invention is that it allows much more accurate estimations of future health care needs and costs. Given a large sample size, it is quite straightforward to determine the typical future costs for each individual in a particular clinical risk group. Those costs then can be used to weight the total cost of a group, based on the number of individuals in each clinical risk group. Similarly, the clinical risk group information can also be used to develop much more accurate predictions of future capital equipment needs, personnel needs and the like.

Brief Description of the Drawings

The preferred embodiments of the invention will be described in connection with the drawings, in which:

Fig. 1 is a schematic of a computer system by which the method of the present invention might be implemented.

Figs. 2-4 are flow charts schematically illustrating the steps of the preferred embodiments of the present invention.

Detailed Description of the Preferred Embodiments

Almost all payers for health care (the government, insurance companies, self-insured companies, etc.) require providers to report on the services for which they are seeking reimbursement using coding schemes, thereby allowing the payers to process the requests for payment efficiently. Most hospitals use the International Classification of Diseases, 9th Revision, Clinical Modifications (ICD-9-CM), to code diagnoses, signs, symptoms, findings and other factors influencing health status. Most professional services and procedures performed in an ambulatory setting are reported using Current Procedural Terminology (CPT) codes and the Health Care Financing Administration (HCFA) Common Procedure Coding Systems (HCPCS), which includes the CPT codes. The present invention therefore will be described with reference to the ICD-9-CM, CPT and HCPCS codes. However, it will be understood that the present invention could be used

with any other suitably detailed coding scheme, and that these coding systems are being used simply because they will be familiar to one of skill in the art.

The present invention analyzes coded medical histories into Clinical Risk Groups (CRGs). Almost of necessity given the size of the databases involved, the process will be implemented in a computer-based system such as that shown in Fig. 1. In Fig. 1, the computer system 100 includes a central processing unit (CPU) 110, random access memory (RAM) 120, mass storage device 130 (such as a hard drive, CD drive, diskette drive or the like), a display 140 (such as a cathode ray tube, LED, LCD or plasma display) and a printer 150 (such as a dot matrix printer, a laser printer, or an ink jet printer), associated such that the CPU can read and write to the RAM 120 and the mass storage device 130, can control the images on the display 140 and the output of the printer 150.

The computer system 100 implements the CRG clinical logic based on a five step or phase process:

- Phase I A disease profile and history of past medical interventions is created.
- Phase II In each organ system, the most significant chronic disease under active treatment is identified
- Phase III In each organ system, the severity of illness level of the most significant chronic disease under active treatment is determined
- Phase IV The most significant chronic disease under active treatment and its associated severity of illness level are combined to determine the overall Base CRG and severity of illness level for the individual
- Phase V The overall Base CRG and severity of illness level are consolidated into three successive tiers of aggregation

As will be seen, the five phase process for determining the CRG assignment identifies individuals with multiple interacting co-morbid diseases and their associated severity of illness level.

Classifications:

The present invention requires creation of a series of classifications, which are generated iteratively -- set up a classification, run test data, analyze the results, modify the classification and repeat. There is no one correct set of classifications -- the particular classifications will change with advancing medical knowledge and other changes affecting

the practice of medicine. Therefore what will be described is the process of creating such a classification system.

In the ICD-9-CM, the term disease is used to encompass diagnoses, signs, symptoms, findings and other factors influencing health status. There are approximately 12,000 codes in the current version of ICD-9-CM. For brevity the ICD-9-CM codes will be referred to simply as disease codes.

Starting with step 200 in Fig. 2, each of the disease codes in the ICD-9-CM are categorized in step 205 into a series of mutually exclusive and exhaustive categories referred to as Major Disease Categories (MDCs). The diseases in each MDC correspond to a single organ system (e.g., respiratory system, digestive system, etc.) or etiology (e.g., malignancies, systemic infectious diseases, etc.). With the exception of malignancies and multiple trauma, which are each assigned to their own MDC, diseases that include both a particular organ system and a particular etiology (e.g., pneumonia) are assigned to the MDC corresponding to the organ system involved. Systemic infections such as septicemia, are assigned to the systemic infections disease MDC. Some diagnoses are considered catastrophic (e.g., persistent vegetative state) and are assigned to a catastrophic MDC. An example of a set of 31 MDCs meeting these criteria is shown in Table 1.

Table 1 – List of MDCs

Class	Description
1	Nervous System Diseases
2	Eye Diseases
3	Ear, Nose, Mouth And Throat Diseases
4	Cranial Facial Anomalies
5	Respiratory Diseases
6	Heart And Cardiac Vascular Diseases
7	Peripheral And Non-Cardiac Vascular Diseases
8	Digestive Diseases
9	Hepatobiliary & Pancreas Diseases
10	Musculoskeletal Diseases
11	Connective Tissue Diseases
12	Skin, Subcutaneous Tissue & Breast Diseases
13	Diabetes

Table 1 – List of MDCs

Class	Description
14	Endocrine, Metabolic And Thyroid Diseases Except Diabetes
15	Kidney And Urinary Tract Diseases
16	Male Reproductive Diseases
17	Female Reproductive Diseases
18	Pregnancy, Childbirth And The Puerperium
19	Newborns And Other Neonates
20	Chromosomal Anomalies, Mental Retardation & Other Developmental Cognitive Diseases
21	Blood And Blood Forming Organ Diseases
22	Malignancies
23	Systemic Infectious And Parasitic Diseases
24	Mental Diseases
25	Substance Abuse
26	Injuries, Poisoning And Toxic Effects Of Drugs
27	Burns
28	Factors Influencing Health Status And Other Contacts With Health Services
29	HIV Infection
30	Multiple Significant Trauma
31	Catastrophic Conditions

The diagnoses in each MDC are further subdivided into Episode Disease Categories (EDCs) in step 210. Each EDC is assigned to one of a number of EDC types, which rate the severity and persistence of the disease.

In a preferred embodiment, there are six EDC types. Four of the EDC types relate to chronic diseases and two of the EDC types relate to acute diseases. A disease is classified as chronic if the duration of the disease is life long (e.g., cystic fibrosis). Diseases which have a prolonged duration, but for which a cure (i.e., no evidence of the disease) is possible, are considered chronic (e.g., malignancies). Life long or prolonged diseases controlled by medication or other means (e.g., hypertension) are also considered chronic. A disease is classified as acute if the duration of the disease is short and the

disease would naturally resolve (e.g., pneumonia) or there is a treatment which cures the disease (e.g., fractured leg). Signs, symptoms and findings (e.g., chest pain) in general are considered acute, even though they might be indicative of a chronic problem. The six preferred EDC types are defined as follows:

- 5 Dominant Chronic EDCs: Serious chronic diseases which usually result in the progressive deterioration of an individual's health and often times lead to, or significantly contribute to an individual's need for medical care, debility and death. (e.g., congestive heart failure, diabetes).
- 10 Moderate Chronic EDCs: Serious chronic diseases which, usually do not result in the progressive deterioration of an individual's health but can significantly contribute to an individual's need for medical care, debility and death (e.g., asthma, epilepsy).
- 15 Minor Chronic EDCs: Chronic diseases which may be serious in their advanced stages or may be a precursor to more serious diseases (e.g., hyperlipidemia), but can usually be managed effectively throughout an individual's life with few complications and minimal effect upon an individual's need for medical care, debility and death (e.g., migraine headache, hearing loss).
- 20 Chronic Manifestation EDCs: A manifestation or acute exacerbation of a chronic disease (e.g., diabetic neuropathy). The chronic manifestation EDC describes manifestation or acute exacerbation (i.e., the neuropathy) and indicates the presence of the underlying chronic disease (i.e., diabetes). In addition, they are used to identify uncommon, but distinct, disease within a more frequently occurring EDC and are used to determine the severity level of the EDC, and for management reporting.
- 25 Significant Acute EDCs: Serious acute illness which can be a precursor to or place the individual at risk for the development of chronic disease (e.g., chest pain) or can result in significant sequelae (e.g., head injury with coma).
- 30

Minor Acute EDCs: Minor acute illnesses are self limiting, are not a precursor to chronic disease, do not place the individual at risk for the development of chronic disease and do not result in significant sequelae (e.g., fractured arm, common cold).

5 The categorization of an EDC as chronic or acute is an important distinction because individuals who have chronic EDCs from multiple organ systems (i.e., MDCs) are assigned to a distinct set of CRGs. Some diseases that are generally considered chronic can, under certain conditions, be an acute disease. For example, congestive heart failure is generally considered a chronic disease. However, congestive heart failure that occurs in
10 children is usually associated with an underlying congenital anomaly which can be corrected by surgery. Therefore, in children congestive heart failure typically would be considered an acute disease. But even this has an exception if the congestive heart failure is due to rheumatic fever, which would always be considered chronic. Similarly, hypertension is generally considered a chronic disease. However, because there is the
15 possibility that a single high blood pressure reading could be miscoded as hypertension, hypertension is considered an acute disease unless the hypertension recurs at least twice over a period of time that spans at least 90 days. Thus, some diseases generally considered chronic are only categorized as chronic under certain conditions.

20 As noted above, procedures performed in hospitals usually are reported using ICD-9-CM procedure codes. Professional services, and procedures performed in an ambulatory setting typically are reported more often as the Current Procedural Terminology (CPT) codes. Prescription drug usage may also be reported in a coded fashion. Like ICD-9-CM codes, at step 215 such procedural codes can be categorized in step 220 according to the present invention into mutually exclusive and exhaustive categories, referred to as Episode
25 Procedure Categories (EPCs). The EPCs can be used to identify individuals who are dependent on some medical technology (e.g., dialysis), who had a procedure that is indicative of advanced disease (e.g., leg amputation) or who had a procedure that has long term sequelae (e.g., heart transplant).

30 The occurrence of EPCs that are indicative of advanced disease or that have long term sequelae are used in step 223 to create a chronic EDC that specifies a history of the procedure (e.g., history of heart transplant). Normally, no distinction need be made

between chronic EDCs associated with the history of a procedure (created in step 223) and chronic EDCs associated with a disease (created in step 210).

As will be apparent, there usually will be hundreds of mutually inclusive and exhaustive EDCs across all of the MDCs. The exact list of EDCs and which disease goes into which EDC will vary with both time and circumstances, and will constantly change over time with changes in medical practice and knowledge. A sample of a possible set of EDCs for the circulatory system is provided in table 2.

Table 2 - EDCs for the Circulatory MDC

Rank	Type	EDC
1	DC	Major Congenital Heart Diseases
2	DC	Moderate Congenital Heart Diseases
3	DC	Congestive Heart Failure
4	DC	Major Chronic Cardiac Diseases
5	DC	Cardiac Valve Diseases
6	DC	History of AMI
7	DC	Angina
8	MC	Atrial Fibrillation
9	MC	Cardiac Dysrhythmia
10	MC	History of CABG
11	MC	History of PTCA
12	MC	History of Cardiac Device
13	MC	Coronary Atherosclerosis
14	MC	Hypertension
15	C	Ventricular and Atrial Sept Defects
16	C	Minor Chronic Cardiac Diseases
	CM	History of Defibrillator
	CM	Unstable Angina
	CM	Moderate Hypertension
	CM	Myocardiopathy
	CM	Pulmonary Hypertension
	CM	Graft Atherosclerosis
	SA	Cyanosis

Table 2 - EDCs for the Circulatory MDC

Rank	Type	EDC
	SA	Ventricular Tachycardia
	SA	Complete Heart Block
	SA	Shock
	SA	Cardiac Arrest
	SA	AMI Except Subendocardial
	SA	Hypotension
	SA	Tachycardia/Palpitation
	SA	Moderate Acute Cardiac Diseases
	SA	Chest Pain
	SA	Subendocardial AMI
	SA	Minor Hypertension
	SA	Pediatric CHF
	MA	Atrial Flutter
	MA	Cardiac Inflammation
	MA	Minor Acute Cardiac Diagnoses
	MA	Malfunction Coronary Bypass Graft
	MA	Complications CV Device, Implant, Graft
	MA	Malfunction CV Device, Implant, Graft
	M	Malfunction Vascular Graft

At step 225 the dominant, moderate and minor chronic EDCs are ranked hierarchically in terms of their relative contribution to an individual's need for medical care, debility and death. Chronic EDCs which result in progressive deterioration of an individual's health are ranked highest in the chronic EDC hierarchy. Table 2 contains the EDCs, the disease type and the chronic EDC rank for the heart and cardiac vascular system MDC.

Next, a process is defined in step 230 to select from the EDCs and EPCs the primary chronic disease (PCD) for each organ system (i.e., MDC), in step 235 a severity of illness (SoI) leveling matrix is created, and in step 240 SoI levels are defined for each

CRG, resulting in the final classification system in step 245. The PCD, SoI leveling matrix and SoI levels will be discussed in more detail below.

After setting initial criteria for the classification system, the initial criteria preferably are tested against real data sets to determine their accuracy. For initial testing, one approach is to Base CRG/SoI assignments on the first year or two of data, then check how that correlates to expenditures in the third year of data. Since, in general, individuals with high healthcare expenditures have significant disease, future expenditures can stand at least initially as a proxy for the individual's clinical condition.

Ultimately, however, detailed reports should be produced which examine the impact of a wide range of clinical characteristics on individuals with specific disease and combinations of diseases. For example, a report might examine the impact on subsequent expenditures of pneumonia in an individual with emphysema, over the most recent six months, or having occurred multiple times. Analysis of these reports then should be fed back into the different categories and how they are adjusted.

While steps in creating the classification system have been defined in a particular order, it will be understood that many of them can be shuffled. For example, instead of first defining the MDCs, then sub-dividing them into EDCs, and developing SoI ratings for the EDCs, it is perfectly possible to first define the EDCs, then group them into MDCs, and develop the SoI ratings either before or after the grouping. The important point is that in the end the classification system has the necessary components, not the particular order in which they are created.

Phase I:

Phase I involves applying the various classifications in the classification system to the medical history of each individual in a group to define a chronic disease profile and history of past medical interventions for each individual. To start, refer to Fig. 3, where a classification system 300 (of the type which is the end result in step 245) is applied to a set of individual data 305 in step 310 to determine the EDCs and EPCs assigned to the individual, i.e., the EDCs and EPCs which code for medical care which has been provided to the patient at some time in the past.

Once the EDCs and EPCs have been assigned, EDCs and EPCs are added or deleted in step 315 based on the nature of and the temporal relationship among the EDCs and EPCs. There are a variety of ways in which these relationships are expressed. The

crucial distinction is that this is done using clinically based conditionality which recognizes the interdependence of EDCs and EPCs. The process design for this step is such as to eliminate the impact of the order in which the conditions are considered, so as to ensure consistent results. One preferred way to do this is to start by creating EDCs, then to adjust for temporal effects and eliminate EDCs and EPCs which are clinically irrelevant. For example, as follows:

Create Chronic EDCs from Chronic Manifestation EDCs: All chronic manifestation

EDCs create a chronic EDC that specifies the underlying chronic disease associated with the manifestation or acute exacerbation. For example, the diabetic neuropathy chronic manifestation EDC creates the diabetes EDC.

Create Chronic EDCs from Multiple Occurrences of an Acute EDC: Selected acute EDCs

that have multiple occurrences over a period of time create a chronic EDC that indicates the recurrence of the acute EDC. For example, if the acute EDC for urinary tract infection occurs at least three times over a period of time that spans at least 180 days, the chronic EDC for recurrent urinary tract infection is created.

Significant Acute EDCs Create Chronic EDCs: Selected significant acute EDCs create a

chronic EDC for the history of the significant acute EDC. For example, the significant acute EDC for AMI creates a chronic EDC for the history of the AMI. A history of a significant acute EDC is only created for significant acute EDCs that indicate a significant progression of an underlying disease (e.g., CVA) or have long term sequelae (e.g., hip fracture). The creation of a chronic EDC for the history of a significant acute EDC is sometimes dependent on the patient's age. The acute EDC for hip fracture only creates the chronic EDC for history of hip fracture if the individual is 65 years or older.

Major Procedure EPCs Create Chronic EDCs: Selected major procedures that are

indicative of advanced disease or have long term sequelae create a chronic EDC for the history of the major procedure. For example, the EDC for coronary bypass surgery creates the chronic EDC for history of coronary bypass surgery.

Temporal Relationship Between EDCs: If specific EDCs occur prior to the first occurrence of another specified EDC, the EDC is eliminated. For example, if the CVA EDC occurs prior to the first occurrence of the hemiplegia EDC, the CVA EDC is eliminated because the hemiplegia is a sequelae of the CVA. However, if a CVA occurs after the first occurrence of hemiplegia, the CVA EDC is not eliminated since it represents a second CVA. The temporal relationship between CVA and hemiplegia is the basis for determining whether there has been a second CVA.

Temporal Relationship Between EDCs and EPCs: If specific EDCs occur prior to the occurrence of a specified EPC, the EDC will be eliminated. For example, if the angina EDC occurred prior to the coronary bypass EPC, the angina EDC is eliminated because the coronary bypass is expected to cure the angina. However, if angina occurs after the coronary bypass EPC, the angina EDC is not eliminated since it indicates that the coronary bypass was not successful.

Temporal Relationship Between EPCs: If a specific EPC occurs prior to the occurrence of another specified EPC, the EPC will be eliminated. For example, if a dialysis EPC occurs prior to a kidney transplant EPC, the dialysis EPC is eliminated because the kidney transplant is expected to eliminate the need for dialysis. However, if dialysis occurs after the kidney transplant EPC, the dialysis EPC is not eliminated since it indicates that kidney transplant was not successful.

The result of this Phase I analysis at step 320 is a complete list of EDCs and EPCs which describes each individual's disease profile and history of past medical interventions.

Phase II:

In Phase II, the EDC that represents the most significant chronic disease for which an individual is under active treatment, referred to as the primary chronic disease (PCD), is identified for each organ system (i.e., MDC).

An underlying assumption of the present invention is that individuals with co-morbid diseases from multiple organ systems constitute the individuals who have poor outcomes and require significant medical care. A single disease (i.e., EDC) therefore is

selected from each major organ system (i.e., MDC) for the purpose of identifying the individuals with co-morbid disease in multiple organ systems.

The first step 325 in Phase II is to reduce the number of chronic EDCs in an MDC that are candidates to be the PCD. Certain chronic diseases are secondary to (i.e., a by-product of or an integral part of) another chronic disease. For example, when asthma and chronic bronchitis are both present, the chronic bronchitis is secondary to the asthma and the primary disease is asthma. In this example, chronic bronchitis is not assigned as the PCD if asthma is present.

The next step 330 in selecting the PCD is to eliminate from consideration as the PCD chronic EDCs that are secondary to another chronic EDC. If only one chronic EDC in an MDC remains after the chronic EDCs that secondary to another chronic EDC are eliminated, then that chronic EDC is the PCD for the MDC.

If more than one chronic EDC remains in the MDC, then the PCD selection criteria defined in step 230 are used to select the PCD. Table 3 provides an example of such a set of PCD selection criteria. In addition to the EDC type, the PCD selection criteria uses the site of service, recency and duration of treatment to select the PCD. An underlying assumption to this ranking is that the diseases that are under recent active treatment have the greatest impact on the subsequent need for medical care, debility and death.

Table 3 - PCD Selection Criteria

EDC Type	Site of Service	Recency of Treatment	Duration of Treatment
Dominant Chronic	Hospital	Last Year	
Dominant Chronic	Ambulatory	Last Year	90 days
Dominant Chronic			
Moderate Chronic	Hospital	Last Year	
Moderate Chronic	Ambulatory	Last Year	90 days

The selection criteria in Table 3 are applied hierarchically from top to bottom. The chronic EDC that meets the highest criteria in the PCD selection hierarchy is selected as the PCD. If more than one EDC meets a selection criteria then the EDC rank in the MDC is used to select the EDC to be the PCD.

Within an EDC type, treatment in a hospital within the most recent year is highest in the selection hierarchy, followed by treatment in an ambulatory setting that had a duration of at least 90 days within the most recent year. Based on the PCD selection criteria, a moderate chronic EDC cannot be selected as the PCD if a dominant chronic EDC is present, and a minor chronic EDC can not be selected as the PCD if a moderate chronic EDC is present. However, within an EDC type, a lower ranking EDC can be selected as the PCD if it has been under active treatment in the past year.

At the end of Phase II, a list 335 of a PCD for each MDC that has at least one chronic EDC present has been determined.

Phase III:

In Phase III the PCD from each MDC is assigned a severity of illness level which for brevity, is referred to as the severity level or Sol. The severity level explicitly describes the extent and progression of the disease selected as the PCD. A high level of severity is indicative of poor prognosis, a high degree of treatment difficulty and a need for substantial medical care in the future.

The severity level of a PCD is determined based on the presence of other EDCs and EPCs. The severity level is primarily determined by the other chronic and acute EDCs that are present from the same MDC as the PCD. Chronic EDCs from other MDCs are used for severity leveling only when the EDC from the other MDC is, with a high degree of confidence, caused by the PCD. For example, malabsorption is caused by cystic fibrosis. Thus, the EDC associated with the malabsorption is used to assign the severity level for a cystic fibrosis PCD. Although a CVA is more likely to occur in an individual with diabetes, the diabetes does not cause the CVA and, therefore, the chronic EDC for history of CVA is not used to determine the severity level of a diabetes PCD.

Acute EDCs from any MDC are used to determine the severity level of the PCD. In particular, acute infections, neurological and gastrointestinal EDCs are used in the severity leveling as an indication of the general health status of the individual. The previous performance of a procedure associated with the treatment of the PCD is used in severity leveling when the procedure is indicative of advance disease or has long term sequelae.

Since any chronic EDC can be a PCD, all chronic EDCs have a severity leveling matrix, as defined in step 240. The severity leveling matrix consists of a list of EDCs and

EPCs. Along with the list of EDCs and EPCs are the conditions or rules under which each EDC and EPC in the list results in a specific severity level. For example, an individual with a PCD of congestive heart failure who had been hospitalized with cardiac valve disease in the most recent year or had been treated at any site for a cardiac valve disease in the most recent six months is considered to have congestive heart failure at severity level 4. However, if the individual had cardiac valve disease, but had not been hospitalized for the cardiac valve diagnosis during the most recent year nor had been treated at any site for the cardiac valve disease during the most recent six months, then the individual is considered to have congestive heart failure at severity level 3. Thus, the severity level associated with the cardiac valve disease differs depending on conditions relating to recency of treatment and the site of treatment.

In addition to the recency and site of treatment, conditions used in the severity leveling matrices can relate to the duration of treatment or the age of the patient. Thus, there is a unique severity leveling matrix for each chronic EDC.

As an example, a severity leveling matrix for congestive heart failure is shown in Table 4. The EDCs at severity level 4 are primarily acute cardiac events (shock, cardiac arrest, acute myocardial infarction (AMI), unstable angina and ventricular tachycardia) that meet the condition of being recent or having required inpatient care. In addition, severity level 4 includes the recent occurrence of acute EDCs that are indicative of advanced congestive heart failure (pleural effusion and hypotension). Co-morbid cardiac diseases (cardiac valve disease, congenital heart disease, and major chronic cardiac diseases) that interact with the congestive heart failure and increase treatment difficulty are also included at severity level 4. Finally, EDCs and EPCs (tracheostomy) that relate to the dependence on a respirator are included at severity level 4.

Table 4 - Severity Leveling Matrix For Congestive Heart Failure

Severity Level	EPC	Type	Recency	Site	Duration
4	Cardiac Valve Diseases	DC	2 Years	Inpatient	
4	Cardiac Valve Diseases	DC	6 Months		
4	Moderate Congenital Heart Diseases	DC	2 Years		
4	Major Congenital Heart Diseases	DC	2 Years	Inpatient	
4	Major Chronic Cardiac Diseases	DC	2 Years	Inpatient	

Table 4 - Severity Leveling Matrix For Congestive Heart Failure

Severity Level	EPC	Type	Recency	Site	Duration
4	History of AMI	DC	6 Months		
4	Unstable Angina	CM	1 Year		90 Days
4	Unstable Angina	CM	1 Year	Inpatient	
4	Pleural Effusion	SA	1 Year		
4	Hypotension	SA	6 Months		
4	Shock	SA	1 Year		
4	Cardiac Arrest	SA	1 Year		
4	Ventricular Tachycardia	SA	6 Months		
4	Ventricular Tachycardia	SA	1 Year	Inpatient	
4	Dependence on Respirator	MA	1 Year		
4	Permanent Tracheostomy	EPC	2 Years		
4	Temporary Tracheostomy	EPC	2 Years		
3	Cardiac Valve Diseases	DC	2 Years		
3	Major Congenital Heart	DC	2 Years		
3	Major Chronic Cardiac Diseases	DC	2 Years		
3	History of AMI	DC	2 Years		
3	Atrial Fibrillation	MC	2 Years		90 Days
3	History of PTCA	MC	2 Years		
3	Cardiac Dysrhythmia	MC	2 Years		90 Days
3	Cardiac Dysrhythmia	MC	6 Months		
3	Coronary Atherosclerosis	MC	6 Months		
3	Unstable Angina	CM	1 Year		
3	History of Defibrillator	CM	2 Years		
3	Graft Atherosclerosis	CM	2 Year		
3	Convulsions	SA	1 Year		90 Days
3	Moderate Neurological SSFs	SA	1 Year		90 Days
3	Extreme Neurological SSFs	SA	1 Year		90 Days
3	Pulmonary Emboli	SA	1 Year		
3	Subendocardial AMI	SA	1 Year		

Table 4 - Severity Leveling Matrix For Congestive Heart Failure

Severity Level	EPC	Type	Recency	Site	Duration
3	Thrombophlebitis	SA	1 Year		90 Days
3	AMI Except Subendocardial	SA	1 Year		
3	Moderate Acute Cardiac Diseases	SA	6 Months		
3	Complete Heart Block	SA	1 Year		
3	Nausea, Vomiting & Diarrhea	SA	1 Year		90 Days
3	Malfunction Coronary Bypass Graft	MA	1 Year		
3	Wheelchair	MA	1 Year		
3	Metabolic / Endocrine Diseases	MA	6 Months		
3	Mechanical Ventilation	EPC	2 Years		
3	Respiratory Therapy	EPC	2 Years		90 Days
3	Hospital Bed	EPC	2 Years		
3	Wheelchair (Motorized)	EPC	2 Years		
2	Angina	DC	2 Years		
2	History of CABG	MC	2 Years		
2	Atrial Fibrillation	MC	2 Years		
2	Minor Chronic Artery & Vein Diseases	C	1 Year		90 Days
2	Obesity	CM	2 Years		
2	Moderate Neurological SSFs	SA	1 Year		
2	Extreme Acute Neurological Diseases	SA	1 Year		
2	Chest Pain	SA	1 Year		90 Days
2	Hypotension	SA	1 Year	Inpatient	
2	Significant GI Diagnoses	SA	1 Year		
2	Minor Acute GI Diagnoses	SA	1 Year		
2	Acute Pancreatitis	SA	1 Year		
2	Hypovolemia	SA	1 Year	Inpatient	
2	Cellulitis	SA	1 Year		90 Days
2	Major Infections	SA	6 Months		

Table 4 - Severity Leveling Matrix For Congestive Heart Failure

Severity Level	EPC	Type	Recency	Site	Duration
2	Major Acute Mental Health Diseases	SA	6 Months		
2	High Mortality Acute Diseases	SA	1 Year		
2	Cardiac Inflammation	MA	1 Year	Inpatient	
2	Atrial Flutter	MA	1 Year		
2	Acute Skin Diagnoses	MA	1 Year		90 Days
2	Minor Bacterial Infections	MA	1 Year		90 Days
2	Minor Infection	MA	6 Months		
2	Coronary Bypass	EPC	2 Years		
2	Major Cardiac Procedure	EPC	2 Years		
2	Permanent Cardiac Pacemaker	EPC	2 Years		
2	Oxygen Therapy	EPC	2 Years		
2	Walkers	EPC	2 Years		
2	Commode	EPC	2 Years		
2	Wheelchair (Standard)	EPC	2 Years		
1	Hypertension	MC	2 Years		
1	Cardiac Dysrhythmia	MC	2 Years		
1	History of Cardiac Device	MC	2 Years		
1	Coronary Atherosclerosis	MC	2 Years		
1	Ventricular and Atrial Sept Defects	C	1 Year		
1	Minor Chronic Cardiac Diseases	C	1 Year		
1	Chest Pain	SA	1 Year		
1	Cyanosis	SA	1 Year		
1	Minor Hypertension	SA	1 Year		
1	Pediatric CHF	SA	1 Year		
1	Tachycardia/Palpitation	SA	1 Year		
1	Moderate Acute Cardiac Diseases	SA	1 Year		
1	Malfunction CV Device, Implant, Graft	MA	1 Year		
1	Minor Acute Cardiac Diseases	MA	1 Year		

Table 4 - Severity Leveling Matrix For Congestive Heart Failure

Severity Level	EPC	Type	Recency	Site	Duration
1	Complications CV Device, Implant, Graft	MA	1 Year		
1	Cardiac Inflammation	MA	1 Year		
1	Malfunction Vascular Graft	M	1 Year		

Severity level 3 for congestive heart failure includes some of the same EDCs as level 4 (AMI, unstable angina, major chronic cardiac disease and congenital heart disease) but without the conditions of being recent or requiring inpatient care. Other moderate cardiac or circulatory EDCs are included at severity level 3 (complete heart block, cardiac dysrhythmia, thrombophlebitis, atrial fibrillation, coronary atherosclerosis, pulmonary emboli, history of coronary bypass and history of defibrillator). Recent acute endocrine, metabolic and neurological problems are also included at severity level 3 since they can be associated with advanced congestive heart failure. Finally, the presence of EPCs that are indicative of significant debility such as a hospital bed for the home or the need for a motorized wheelchair are included at severity level 3.

Severity level 2 for congestive heart failure includes some acute cardiac EDCs (chest pain, atrial flutter, stable angina and cardiac inflammation) plus some of the moderate cardiac or circulatory EDCs from severity level 3 (e.g., atrial fibrillation without the condition of having a duration of at least 90 days). Severity level 2 also includes a wide range of acute problems from other MDCs (e.g., infections, mental health diagnoses, skin diagnoses, etc.) that are indicative of general health status. Finally, an extended list of history of significant cardiac procedures (e.g., cardiac pacemaker) and EPCs related to medical supplies that are indicative of debility (e.g., walker, commode) are included at severity level 2.

If none of the EDCs and EPCs and associated conditions in severity levels 2 through 4 are present, then the congestive heart failure PCD is assigned severity level 1. For completeness, all the EDCs in the heart and cardiac vascular MDC that are not used in severity levels 2 through 4 are included in level 1 in the severity leveling matrix for

congestive heart failure. However, since severity level 1 is the default severity level, a severity of level 1 can be assigned without any of the EDCs listed in level 1 being present.

The number of severity levels specified in the severity leveling matrix may vary across EDCs. Minor chronic EDCs and non-metastatic malignancy EDCs have only two severity levels specified because of the limited clinical spectrum of these diseases. All dominant chronic, moderate chronic and metastatic malignancy EDCs have four severity levels.

The severity level for a PCD is determined based on the following steps:

1. In step 340, use the complete list 320 of EDCs and EPCs created in Phase I to identify the subset of EDCs and EPCs that are present in the severity leveling matrix for the PCD.
2. In step 345, for each EDC and EPC identified in step 340, evaluate the associated conditions in the severity leveling matrix and determine the severity level for each EDC and EPC.
3. In step 350, set the severity level for the PCD equal to the highest severity level associated with any of the EDC and EPCs from step 345.

Since the same EDCs and EPCs can be used in the severity leveling matrix for PCDs in more than one MDC, it is possible that the same EDC or EPC could determine the severity level for more than one PCD. Thus, the presence of a single EDC or EPC could have a disproportionate impact on the overall severity level of the individual. To avoid this possibility, the severity level for each PCD preferably is determined in step 345 with the constraint that no EDC or EPC can determine the severity level (i.e., be the EDC or EPC used in step 3) of more than one PCD.

At the end of Phase III in step 355, all PCDs for an individual have been assigned a severity level.

Phase IV:

In phase IV, the PCD/SoI information is used to identify the CRG Status, Base CRG, and overall SoI. The CRG Status indicates a general overall status for the individual (e.g., anything from catastrophic to healthy). The Base CRG indicates the primary cause for the CRG status (e.g., Heart And Cardiac Vascular Diseases), while the overall SoI correlates to the severity of the Base CRG (e.g., in the hospital, ambulatory)

The individual is assigned to one of a number of CRG Statutes in step 360 based on the PCDs that are present. A preferred embodiment has 9 CRG Statutes:

Catastrophic Conditions: Catastrophic conditions include long term dependency on a medical technology (e.g., dialysis, respirator, TPN) and life-defining chronic diseases that dominate the medical care required (e.g., persistent vegetative state, cystic fibrosis, AIDS, history of heart transplant).

Dominant and Metastatic

Malignancies: A malignancy that dominates the medical care required (e.g., brain malignancy) or a non dominant malignancy (e.g., prostate malignancy) that is metastatic.

Dominant Chronic Disease
in Three or More Organ

Systems: Dominant chronic disease in three or more organ systems is identified by the presence of three or more dominant PCDs.

Significant Chronic Disease

in Multiple Organ Systems: Significant chronic diseases in multiple organ systems is identified by the presence of two or more PCDs of which at least one is a dominant or moderate PCD. PCDs that are a severity level 1 minor chronic disease are not considered a significant chronic disease and are not used to identify the presence of significant chronic disease in multiple organ systems.

Single Dominant or

Moderate Chronic Disease: Single dominant or moderate is identified by the presence of a single dominant or moderate PCD.

Minor Chronic Disease in

Multiple Organ Systems: Minor chronic disease in multiple organ systems is identified by the presence of two or more minor PCDs.

Single Minor Chronic

Disease: A single minor chronic disease is identified by the presence of a single minor PCD.

History of Significant

- Acute Disease: A history of significant acute disease is identified by the presence of one or more significant acute EDCs in the last six months with no PCDs present.
- 5 Healthy: A healthy status is identified by the absence of any PCDs or recent significant acute EDCs or EPCs.

The CRG Status is assigned hierarchically starting with the catastrophic status. The first status in the hierarchy for which the status criteria are met is assigned as the CRG Status.

10 Once the CRG Status is determined, the Base CRG and overall severity level of the individual is determined in step 365. The Base CRG is assigned based on the PCD(s) which are present in the individual's record. The SoI in turn depends on the severity level of those PCDs, and where appropriate, any adjustments applied to the CRG status and Base CRG.

15 Catastrophic Conditions: The first status in the CRG status hierarchy is for individuals with catastrophic conditions associated with long term dependence on medical technology or life-defining chronic diseases that dominate the medical care required. All conditions that are considered catastrophic are ordered hierarchically (e.g., dialysis is higher in the catastrophic hierarchy than history of heart transplant). If there is more than
20 one catastrophic condition present, the catastrophic condition that is highest in the catastrophic hierarchy is assigned as the Base CRG.

For each catastrophic condition there is a four level severity leveling matrix (defined in step 240) that is specific to the catastrophic condition. In addition, since
25 individuals with a catastrophic condition can also have diseases in organ systems that are not directly related to the catastrophic condition, the severity level that is assigned based on the severity leveling matrix specific to the catastrophic condition is adjusted based on the presence of PCDs from organ systems unrelated to the catastrophic condition. The additional adjustment to the severity level is done to insure that the severity level of the catastrophic condition fully reflects to the total burden of illness.

30 Dominant And Metastatic Malignancies: The second status in the CRG status hierarchy is for individuals with dominant or metastatic malignancies. Certain malignancies (e.g., brain, pancreas, etc.) are similar to catastrophic conditions in that they

are life defining and dominate the medical care required. Other malignancies (e.g., prostate, colon, etc.) do not dominate the medical care required unless they are metastatic. When multiple malignancies are present, each malignancy is classified as primary or secondary (e.g., a bone malignancy is considered secondary to a prostate malignancy). A
5 primary malignancy is considered metastatic if there is a related secondary malignancy present.

In addition to identifying a primary metastatic malignancy by the presence of a related secondary malignancy, there are also some conditions that are indicative of an advanced stage of the primary malignancy and are, for all practical purposes, indicative of
10 metastasis (e.g., malnutrition, the need for a second course of chemotherapy, etc.). For each dominant or metastatic primary malignancy there is a four level severity leveling matrix that is specific to the primary malignancy. In addition, since individuals with a dominant or metastatic primary malignancy can also have diseases in organ systems that are not directly related to the primary malignancy, the severity level that is assigned based
15 on the severity leveling matrix specific to the primary malignancy is adjusted based on the presence of PCDs from organ systems unrelated to the primary malignancy. The additional adjustment to the severity level is done to insure that the severity level of the dominant or metastatic primary malignancy fully reflects the total burden of illness. Primary malignancies that are not dominant or metastatic are treated like any other disease and are
20 included in the subsequent portions of the CRG status hierarchy.

Dominant Chronic Disease In Three Or More Organ Systems: The third status in the CRG status hierarchy is for individuals with dominant chronic diseases in three or more organ systems. Explicit combinations of three dominant PCDs are identified (e.g., congestive heart failure, diabetes and emphysema). The explicit combinations of three
25 dominant PCDs are ranked hierarchically. Individuals with three or more dominant PCDs are assigned to a Base CRG that corresponds to the first match in the hierarchy. If the dominant PCDs do not match any of the explicit combinations, then the individual is assigned to a residual Base CRG that corresponds to any combination of three dominant PCDs that are not explicitly specified in the hierarchy.

Each Base CRG that is comprised of three or more dominant PCDs is subdivided
30 in six severity levels. The severity level is determined using the severity level for each of

the PCDs that comprised the CRG. Table 5 provides an example of a suitable matrix to assign the severity of illness.

Table 5 – Severity Levels for CRGs Composed of
Three or More Dominant PCDs

CRG Severity Level	Severity Level of PCDs		
	4	3	2 or 1
6	3 or more		
5	2	1 or more	
4	2	None	1 or more
4	1	2 or more	
3	1	1	1 or more
3	1	None	2 or more
3	1	3 or more	
2		2	1 or more
2		1	2 or more
1		1	3

The criteria in Table 5 are applied hierarchically from top to bottom. The severity level for the CRG is assigned based on the first criteria that is matched in Table 5. For example, if the three dominant PCDs that comprise the CRG have severity levels of 4,4 and 2, then the severity level of the CRG would be 4. The severity level that results from Table 5 is generic to all CRGs, since the same Table 5 applies to all CRGs that are comprised of three more dominant PCDs.

The CRG severity level that results from the application of the generic criteria in Table 5 is then adjusted based on criteria that is specific to that Base CRG. The adjustments reflect that conditions become more complex in the presence of multiple disease processes, or the presence of other complication factors. For example, the generic severity level for the Base CRG comprised of congestive heart failure, diabetes and emphysema is increased by one if the EDC for unstable angina is present and the unstable angina has been actively treated in the most recent six month period. The unstable angina is often treated by performing coronary bypass surgery. However, if the patient also has

diabetes and emphysema the surgical treatment may not be an option resulting in a difficult to treat patient with a probable poor prognosis.

5 Significant Chronic Disease In Multiple Organ Systems: The fourth status in the CRG status hierarchy is for individuals with significant chronic diseases in multiple organ systems. For individuals who do not have three or more dominant chronic diseases but do have multiple chronic diseases with at least one dominant or moderate chronic disease, explicit combinations of two PCDs are identified (e.g., congestive heart failure and diabetes). Severity level 1 minor PCDs are not used in identifying combinations of two significant chronic diseases since they have minimal impact on the individual's need for medical care.

10 The explicit combinations of two PCDs are ranked hierarchically. Individuals with two or more PCDs are assigned to a Base CRG that correspond to the first match in the hierarchy. If the PCDs do not match any of the explicit combinations, then a residual Base CRG is assigned that correspond to any combination of two PCDs that are not explicitly specified in the hierarchy.

15 Each Base CRG that is comprised of two PCDs is subdivided into between 2 and 6 severity levels. Since non-metastatic malignancy PCDs only have two severity levels and since minor PCDs at severity level 1 are not used in the combinations of two PCDs, the number of severity levels depend on the PCDs that comprise the combination. A combination that is comprised of a non-metastatic malignancy PCD and a severity level 2 minor PCD has two severity levels. A combination that is comprised of a dominant or moderate PCD and a severity level 2 minor PCD or a non-metastatic malignancy PCD has four severity levels. All other combinations of PCDs have six severity levels.

20 The severity levels for the CRG is determined using the severity level for each of the PCDs that comprise the combination. Since the individual PCDs that comprise the combination can be very different in terms of relative clinical significance (e.g., the combination of congestive heart failure and diabetes versus the combination of congestive heart failure and glaucoma) the criteria used to determine the severity level for the CRG is specific to the PCDs that comprise the combination. Table 6 shows the severity levels for a CRG composed of the dominant PCD for diabetes and the dominant PCD for congestive heart failure.

Table 6 -- Severity Levels for the CRG that is Comprised of
the PCDs for Congestive Heart Failure and Diabetes

Congestive Heart Failure Severity Level	Diabetes Severity Level			
	4	3	2	1
4	6	5	4	4
3	5	4	3	3
2	4	3	2	2
1	3	2	2	1

Based on the criteria in Table 6, if the diabetes PCD is severity level 3 and the congestive heart failure PCD is severity level 4, the severity level for the CRG is 5.

The CRG severity level that results from the application of criteria like that in Table 6 is further adjusted based on criteria that is specific to that Base CRG. The adjustments reflect that conditions become more complex in the presence of multiple disease process, or the presence of other complication factors. For example, the CRG severity level for the Base CRG comprised of congestive heart failure and diabetes is increased by one if the PCD for chronic gastric ulcer is present and the chronic gastric ulcer has been actively treated in the most recent six month period. Since the gastric ulcer PCD is not a dominant chronic disease the individual is not assigned to one of the CRGs for three dominant chronic diseases. However, the chronic ulcer disease complicates the treatment of the congestive heart failure and diabetes and, therefore, increases the severity level.

Single Dominant Or Moderate Chronic Disease: The fifth status in the CRG status hierarchy is for individuals with a single dominant or moderate chronic disease. These individuals have only one PCD. The Base CRG is the same as the PCD (i.e., if the single PCD for the patient is diabetes, the Base CRG is diabetes). The severity level for the CRG is the same as the PCD severity level. The malignancy PCDs have two severity levels and all other moderate and dominant PCDs have four severity levels.

Minor Chronic Disease In Multiple Organ Systems: The sixth status in the CRG status hierarchy is for individuals with two or more minor chronic diseases. Individuals with two or more minor chronic diseases are assigned to a single Base CRG which has

four severity levels based on the number of minor chronic PCDs present and the severity level of the minor chronic PCDs.

Single Minor Chronic Disease: The seventh status in the CRG status hierarchy is for individuals with a single minor chronic disease. These individuals have only one PCD. The Base CRG is the same as the PCD. The severity level for the CRG is the same as the PCD severity level.

History Of Significant Acute Disease: The eighth status in the CRG status hierarchy is for individuals with a history of significant acute disease. The individual has no PCDs present but at least one significant acute EDC is present. If the significant acute EDC (e.g., AMI) creates a chronic EDC for the history of the significant acute (e.g., history of AMI) then the individual would have a PCD present and, therefore, would not be assigned to the status for history of significant acute disease. Thus, individuals with significant acute diseases with significant sequelae such as AMI are not included in this status. However, the significant acute diseases that are present in this status can be a precursor to chronic disease or place the individual at risk for the development of chronic disease (e.g., chest pain). Thus, although the patients in the history of significant acute disease status do not have any chronic diseases, they are distinct from healthy individuals.

Certain EPCs are also considered equivalent to a significant acute disease. For example, if the skin graft EPC is present, the individual is assigned to the history of significant acute disease status even if no significant acute EDCs are present. The performance of a skin graft is considered indicative of a history of significant acute disease. There are a number of Base CRGs, e.g., six, for individuals with history of significant acute disease. The Base CRGs are determined based on the number and duration of the significant acute diseases present. There are no severity levels assigned to the history of significant acute disease CRGs.

Healthy: The ninth and final status in the CRG status hierarchy is for healthy individuals who have no PCDs and no significant acute EDCs or EPCs. They may have minor acute EDCs present (e.g., common cold) but are otherwise healthy. There is a single CRG for healthy individuals.

The end result of phase IV is a CRG/Sol for the individual, at 370. Individual CRG/Sol data can be used for a variety of purposes, most notably as a very shorthand

description of the overall health condition of the individual, but are most useful when analyzed in groups, in phase V.

Phase V:

For higher level reports, it is useful to aggregate the CRG levels into smaller sets of risk groups. In step 410, the starting point for this is the CRG/Sols developed for an individual in phases I to IV. Phase V then consolidates the CRGs into successive tiers of aggregation, preferably three tiers. Each successive tier of aggregation has fewer Base CRGs. Across the CRG aggregations, the CRG Status and the severity levels within the aggregated CRGs are maintained. Thus, the successive tiers of CRG aggregation maintain the CRG Status and maintain the severity levels but reduce the number of Base CRGs.

Although the aggregation of CRGs reduces clinical precision, the successive tiers of aggregation maintain clinical meaningfulness (in contrast to past practices focussing just on cost). The successive tiers of aggregation take into consideration the future medical care needs and clinical similarity of the individuals assigned to the aggregated CRGs. The aggregated CRGs are referred to as ACRGs and the successive tiers of aggregation may be referred to with suitable designators, e.g., ACRG1, ACRG2 and ACRG3, with ACRG3 being the highest level of aggregation. Table 7 provides an example of summarizes the aggregation of CRGs into ACRGs.

Table 7 -- Aggregation of CRGs into ACRGs

CRG Status	CRG	ACRG1	ACRG2	ACRG3
Catastrophic				
Base	11	10	6	1
SoI Levels	4	4	4	6
Total	44	40	24	6
Dominant and Metastatic Malignancies				
Base	23	3	1	1
SoI Levels	4	4	5	4
Total	92	12	5	4

Table 7 -- Aggregation of CRGs into ACRGs

CRG Status	CRG	ACRG1	ACRG2	ACRG3
Dominant Chronic Disease in Three or More Organ Systems				
Base	21	7	2	1
SoI Levels	6	6	6	6
Total	126	42	12	6
Significant Chronic Disease in Multiple Organ Systems				
Base	61	24	8	1
SoI Levels	2,4,6	4,6	5,6	6
Total	324	134	47	6
Single Dominant or Moderate Chronic Disease				
Base	109	25	8	1
SoI Levels	2,4	2,4	2,5,6	6
Total	406	96	35	6
Minor Chronic Disease in Multiple Organ Systems				
Base	1	1	1	1
SoI Levels	4	2	2	2
Total	4	2	2	2
Single Minor Chronic Diseases				
Base	40	21	2	1
SoI Levels	2	2	2	2
Total	80	42	4	2
History of Significant Acute Disease				
Base	6	1	1	1
SoI Levels	1	1	1	1
Total	6	1	1	1

Table 7 -- Aggregation of CRGs into ACRGs

CRG Status	CRG	ACRG1	ACRG2	ACRG3
Healthy				
Base	1	1	1	1
SoI Levels	1	1	1	1
Total	1	1	1	1
Total				
Base	273	93	30	9
SoI Levels	1,2,4,6	1,2,4,6	1,2,4,5,6	1,2,5,6
Total	1083	370	131	34

In the example used in Table 7, the number of Base CRGs are 273, 93, 30 and 9 and the number of CRGs with severity levels are 1083, 370, 131 and 34 for CRG, ACRG1, ACRG2 and ACRG3, respectively.

The process of aggregating CRGs into successive tiers of ACRGs is illustrated in Table 8 for the CRG Status comprising dominant and moderate chronic diseases for the MDCs for heart and coronary vascular diseases, peripheral vascular and non-cardiac vascular diseases and respiratory diseases.

Table 8 -- Aggregation of Cardiopulmonary CRGs into ACRGs for the CRG Status Consisting of a Single Dominant or Moderate Disease

CRGs		ACRG1		ACRG2	
Heart and Coronary Vascular Diseases		Circulatory Diseases		Cardiopulmonary Diseases	
13 Base CRGs x 4 Sol Levels = 54 CRGs		4 Base ACRG1s x 4 Sol Levels = 16 ACRG1s		1 Base ACRG2 x 6 Sol Levels = 6 ACRG2s	
DC	Congestive Heart Failure	DC	Congestive Heart Failure	DC	Congestive Heart Failure
DC	Major Congenital Heart	DC	Congestive Heart Failure	DC	Major Congenital Heart
DC	Moderate Congenital Heart			DC	Moderate Congenital Heart
DC	Major Cardiac Diagnoses	Dominant chronic circulatory diseases except CHF		DC	Major Cardiac Diagnoses
DC	Cardiac Valve Diagnoses			DC	Cardiac Valve Diagnoses
DC	History of AMI			DC	History of AMI
DC	Angina			DC	Angina
MC	Atrial Fibrillation			DC	Peripheral Vascular Disease
MC	Cardiac Dysrhythmia			DC	Moderate Artery and Vein
MC	History of CABG				Disease
MC	History of PTCA			DC	COPD and Bronchiectasis
MC	History of Cardiac Device			DC	BPD/Major Lung Anomaly
MC	Coronary Atherosclerosis			DC	Significant Pulmonary Disease
MC	Hypertension	DC	Moderate Artery and Vein Disease	DC	Tracheostomy Status

Table 8 (cont'd)
(ACRG1 cont'd)

MC	Atrial Fibrillation	(ACRG2 cont'd)
MC	Cardiac Dysrhythmia	
MC	History of CABG	
MC	History of PTCA	
MC	History of Cardiac Device	
MC	Coronary Atherosclerosis	
MC	Leg Varicosities with Ulcer	
MC	Hypertension	
MC	Asthma	

MC	Moderate chronic circulatory diseases except hypertension	
MC	Atrial Fibrillation	
MC	Cardiac Dysrhythmia	
MC	History of CABG	
MC	History of PTCA	
MC	History of Cardiac Device	
MC	Coronary Atherosclerosis	
MC	Leg Varicosities with Ulcer	

MC	Hypertension	
MC	Hypertension	

(CRG cont'd)

Peripheral and Non Cardiac Vascular

Diseases

3 Base CRGs x 4 Sol Levels =

12 CRGs

DC	Peripheral Vascular Disease
DC	Moderate Artery and Vein Disease
MC	Leg Varicosities with Ulcer

Respiratory Diseases

5 Base CRGs x 4 Sol Levels =

20 CRGs

DC	COPD and Bronchiectasis
DC	BPD/Major Lung Anomaly
DC	Significant Pulmonary Disease
DC	Tracheostomy Status
MC	Asthma

Table 8 (cont'd)
(ACRG1 cont'd)

Respiratory Diseases

2 Base ACRG1s x 4 Sol Levels =

8 ACRG1s

Dominant chronic respiratory diseases	
DC	COPD and Bronchiectasis
DC	BPD/Major Lung Anomaly
DC	Significant Pulmonary Disease
DC	Tracheostomy Status

Asthma	
MC	Asthma

As shown in Table 8, in these three MDCs there are 24 Base CRGs, each with 4 severity levels for a total of 96 CRGs. In step 415, the CRGs are aggregated into ACRG1s by combining the MDCs for heart and coronary vascular disease together with the MDC for peripheral vascular and non-cardiac vascular disease into “circulatory diseases”, which is subdivided into the following four circulatory base ACRG1s.

- Congestive heart failure
- Dominant chronic circulatory diseases except CHF
- Moderate chronic circulatory diseases except hypertension
- Hypertension

Similarly, the CRGs in the respiratory system are aggregated into two base ACRG1s

- Dominant chronic respiratory diseases
- Asthma

Thus, the 24 Base CRGs from these three MDCs are consolidated into six base ACRG1s.

The severity level for the ACRG1 is determined in step 420. It is the same as the severity level for the CRG (e.g., if the severity for the angina CRG is level 3, the severity level for the ACRG1 for dominant chronic circulatory diseases except CHF is also level 3). Thus, the 96 CRGs in these three MDCs for the single dominant or moderate chronic disease status are aggregated into 24 ACRG1s.

In step 425, the six Base CRGs in ACRG1 are aggregated into a single ACRG2 for cardiopulmonary disease. However, because there is significant clinical diversity across the six ACRG1s, the number of severity levels in ACRG2 is expanded to six. The mapping of the four severity levels for the ACRG1s to the six severity levels for the ACRG2s is shown in Table 9.

Table 9 – Mapping of ACRG1 Severity Level to ACRG2 Severity Level for
Cardiopulmonary Diseases

Base ACRG1	ACRG2 severity Level					
	1	2	3	4	5	6
Congestive Heart Failure			1	2	3	4
Dominant Chronic Circulatory System Diseases except CHF		1	2	3	4	
Dominant Chronic Respiratory Diseases			1	2	3	4
Moderate Chronic Circulatory System Diseases except Hypertension	1	2	3	4		
Hypertension		1	2	3	4	
Asthma	1	2	3	4		

Severity level 6 for cardiopulmonary base ACRG2 is composed of ACRG1 severity level 4 congestive heart failure and ACRG1 severity level 4 dominant chronic respiratory diseases. The mapping of the ACRG1 severity levels to the ACRG2 severity levels in step 430 reflects both the ACRG1 severity level and the relative clinical significance of the different base ACRG1s that are aggregated into a single base ACRG2.

In step 430, all base ACRG2s in the single dominant or moderate chronic disease status are aggregated into a single base ACRG3 with six severity levels. Similar to the severity level mapping between ACRG1 and ACRG2, in step 440, there is a severity level mapping between ACRG2 and ACRG3 that reflects the relative clinical significance of the different base ACRG2s that are aggregated into the single base ACRG3. The end result in step 445 is a set of ACRG/SoI ratings for the individuals using ever smaller sets of Base CRG categories.

The clinical logic in the five phase process for determining CRG assignment results in a severity adjusted set of mutually exclusive and exhaustive categories that differentiate the relative need for medical care as well as debility and death. The multiple aggregations of CRGs provide the flexibility for CRG to be used at a level of detail that corresponds to the needs of all users including payers and providers. Since the successive consolidations of CRGs are formed in a hierarchical manner, upper management can

receive highly aggregated reports, while clinicians can receive a corresponding set of reports that contain more details.

5 The CRGs can be used in several ways to project future costs, by computing the average future cost of individuals assigned to each CRG, and weighting total costs for a group based on the number of individuals in each CRG. For example, suppose two years of historical data were available. CRGs would be assigned based on the demographic and clinical information in the first year. CRG payment weights would be computed as the average expenditures in the second year for individuals assigned to each CRG based on the first year data. Thus, the first year of data is used to assign the CRG and the second
10 year is used to compute the CRG payment weight. The separation of the CRG clinical model and the CRG payment weights allows payers to compute their own payment weights while using the standard CRG clinical model.

15 The CRGs also are very useful in projecting costs for different mixes of coverage. The specific categories of expenditures included in capitated payment arrangements can vary. For example, pharmacy costs may be carved out of the capitated rate. The CRG payment weights can be expressed in terms of the cost components that make up the payment weight (e.g., pharmacy, physician, hospital, laboratory, etc.) so that the proportion of the payment weight that is associated with each cost component is known. For example, a capitated payment arrangement negotiated with a managed care
20 organization might exclude pharmacy expenditures, which could be paid on a capitated basis to a separate organization. CRG payment weights excluding pharmacy and separate CRG pharmacy payment weights can be generated to support such a payment arrangement. The separation of the clinical model and payment weights, and the relatively straight-forward method for computing the CRG payment weights (i.e., the average values
25 for each CRG) provides great flexibility in establishing capitated payment arrangements.

30 The multiple levels of aggregated CRGs also make the CRGs useful in calculating payment weights for relatively small groups. Payers that wish to compute their own payment weights but have relatively few covered individuals can use a highly consolidated tier of CRG aggregation in order to have a sufficient number of covered individuals in each ACRG to compute a payment weight.

It will be understood that these exemplary embodiments in no way limit the scope of the invention. Other modifications of the invention will be apparent to those skilled in

the art in view of the foregoing description. These descriptions are intended to provide specific examples of embodiments which clearly disclose the present invention.

Accordingly, the invention is not limited to the described embodiments or to the use of specific elements, dimensions, materials or configurations contained therein. All

5 alternative modifications and variations of the present invention which fall within the spirit and scope of the appended claims are covered.

0030235-04299

Claims

We claim:

1. A method of creating a classification system for medical care, comprising:
 - a) obtaining a set of medical care codes;
 - b) categorizing the medical care codes into major disease categories;
 - c) categorizing the medical care codes into episode disease categories based on the severity and persistence of the disease, and assigning each episode disease category to a major disease category; and
 - d) sub-dividing at least some of the episode disease categories by severity of illness.
2. The method of claim 1, further comprising defining a set of severity of illness levels for each episode disease category.
3. The method of claim 1, wherein at least some of the episode disease categories represent chronic conditions, and only the chronic episode disease categories are sub-divided by severity of illness.
4. The method of claim 1, further comprising defining a severity of illness leveling matrix for adjusting the severity of illness level for each episode disease category based on the nature and timing of treatment for each episode disease category.
5. The method of claim 3, further comprising:
 - a) providing a second set of medical care codes;
 - b) categorizing the medical care codes in the second set into episode procedure categories;wherein the severity of illness leveling matrix takes account of the episode procedure categories in adjusting the severity of illness level for each episode disease category.
6. The method of claim 5, further comprising the step of creating episode disease categories which are indicated by episode procedure categories.
7. The method of claim 1, further comprising defining criteria for aggregating the episode disease categories and severity of illness levels to assign an overall clinical risk group and severity of illness rating to an individual patient.
8. The method of claim 7, further comprising defining a set of selection criteria for selecting a primary chronic disease from the episode disease categories for each major disease category.

9. The method of claim 7, wherein the selection criteria for selecting the primary chronic disease comprise:

- a) ranking the episode disease categories in each major disease category by severity;
- b) adjusting the ranking based on the presence and severity of episode disease categories in other major disease category;
- c) selecting as the primary chronic disease the highest adjusted rank episode disease category in each major disease.

10. The method of claim 7, wherein the criteria assigning the overall clinical risk group comprise:

- a) defining criteria for a series of risk groups ranked in order of declining severity;
- b) comparing the primary chronic diseases to the criteria for each risk group, and assigning the most severe clinical risk group for which the criteria are met.

11. The method of claim 10, wherein the clinical risk groups comprise:

- a) catastrophic conditions;
- b) dominant and metastatic malignancies;
- c) dominating chronic disease three or more organ systems;
- d) significant chronic disease in multiple organ systems;
- e) single dominant or moderate chronic disease;
- f) minor chronic disease in multiple organ systems;
- g) single minor chronic disease;
- h) history of significant acute disease; and
- i) healthy.

12. The method of claim 7, further comprising defining criteria for aggregating the clinical risk group and severity of illness rating to assign at least one aggregated clinical risk group and severity of illness rating to a group of patients.

13. A method of applying the classification system of any of claims 1 through 12, comprising:

- a) obtaining historical care data for an individual;
- b) determining the episode disease categories for the individual;
- c) adjusting the episode disease categories for the individual based on the nature and temporal relationships of the episode disease categories experienced by the individual.

14. The method of claim 13, wherein the adjustment step includes deleting episode disease categories when the temporal relationship between events implies that the disease indicated by an episode disease category has likely been eliminated by subsequent treatment.

15. The method of claim 13, wherein the adjustment step includes adding episode disease categories when the presence of multiple episode disease categories implies the presence of an underlying episode disease category.

16. The method of claim 13, further comprising the step of assigning a clinical risk group to the individual based on the adjusted episode disease categories experienced by the individual.

17. The method of claim 16, further comprising the steps of:

- a) identifying from adjusted episode disease categories the primary chronic disease in each major disease categories; and
- b) determining the clinical risk group based on the primary chronic diseases.

18. The method of claim 17, further comprising the steps:

- a) determining the severity of illness level for each episode disease category experienced by the individual;
- b) setting an initial severity of illness level for each major disease category to the severity of illness level for the primary chronic disease for that major disease category;
- c) adjusting the severity of illness level based on the nature, temporal relationships and severity of illness levels of the episode disease categories experienced by the individual; and
- d) assigning an overall severity of illness for the individual based on the adjusted severity of illness levels for the major disease categories experienced by the individual.

19. The method of claim 13, further comprising the steps of:

- a) using the criteria for aggregating the clinical risk groups to aggregate the individuals clinical risk group into an aggregated clinical risk group;
- b) using the criteria for aggregating severity of illness to determine the severity of illness of the aggregated clinical risk group.

20. The method of claim 19, further comprising the step of repeating steps (b) and (c) in claim 19 to further aggregate the aggregated clinical risk groups.

21. The method of claim 13, further comprising the steps of:

- a) repeating steps (a) through (c) for a plurality of individuals to assign a historical clinical risk group representative of what their clinical risk group would have been at a prior time;
- b) analyzing the historical care data for a pre-determined time period after the prior time to determine the average cost of providing health care to all individuals in each historical clinical risk group during the time period; and
- c) projecting future costs for the plurality of individuals by weighting the average costs for each historical risk group by the number of people currently in each clinical risk groups.

22. Computer storage media containing software which, when executed by a computer, will cause the computer to implement the method of claim 13.

23. A computer comprising a central processing unit programmed to apply the classification system of any of claims 1 through 20, by implementing method, comprising:

- a) obtaining historical care data for an individual;
- b) determining the episode disease categories for the individual;
- c) adjusting the episode disease categories for the individual based on the nature and temporal relationships of the episode disease categories experienced by the individual.

24. The computer of claim 23, wherein the adjustment step includes deleting episode disease categories when the temporal relationship between events implies that the disease indicated by an episode disease category has likely been eliminated by subsequent treatment.

25. The computer of claim 23, wherein the adjustment step includes adding episode disease categories when the presence of multiple episode disease categories implies the presence of an underlying episode disease category.

26. The computer of claim 23, wherein the method further comprises the step of assigning a clinical risk group to the individual based on the adjusted episode disease categories experienced by the individual.

27. The computer of claim 26, wherein the method further comprises the steps of:
a) identifying from adjusted episode disease categories the primary chronic disease in each major disease categories; and

b) determining the clinical risk group based on the primary chronic diseases.

28. The computer of claim 27, wherein the method further comprises the steps of:

a) determining the severity of illness level for each episode disease category experienced by the individual;

b) setting an initial severity of illness level for each major disease category to the severity of illness level for the primary chronic disease for that major disease category;

c) adjusting the severity of illness level based on the nature, temporal relationships and severity of illness levels of the episode disease categories experienced by the individual; and

d) assigning an overall severity of illness for the individual based on the adjusted severity of illness levels for the major disease categories experienced by the individual.

29. The computer of claim 23, wherein the method further comprises the steps of:

a) using the criteria for aggregating the clinical risk groups to aggregate the individuals clinical risk group into an aggregated clinical risk group;

b) using the criteria for aggregating severity of illness to determine the severity of illness of the aggregated clinical risk group.

30. The computer of claim 29, wherein the method further comprises the step of repeating steps (b) and (c) in claim 29 to further aggregate the aggregated clinical risk groups.

31. The computer of claim 23, wherein the method further comprises the steps of:

a) repeating steps (a) through (c) for a plurality of individuals to assign a historical clinical risk group representative of what their clinical risk group would have been at a prior time;

b) analyzing the historical care data for a pre-determined time period after the prior time to determine the average cost of providing health care to all individuals in each historical clinical risk group during the time period; and

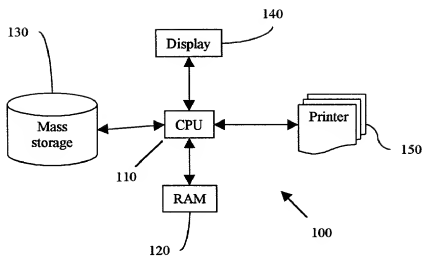
- c) projecting future costs for the plurality of individuals by weighting the average costs for each historical risk group by the number of people currently in each clinical risk groups.

Method of Grouping and Analyzing Clinical Risks, and System Therefor

Abstract of the Disclosure

5 A comprehensive set of risk groups explicitly identifies groups of individuals with multiple interacting co-morbid conditions, and which explicitly identifies the severity of illness level. This allows accurate prediction of future health care resource needs of an entire population, while simultaneously helping the health care provider isolate problems to identify changes in care to reduce costs and improve quality.

Fig. 1



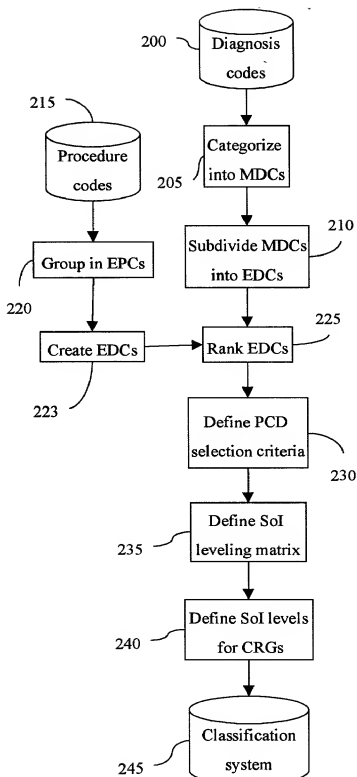


Fig. 2

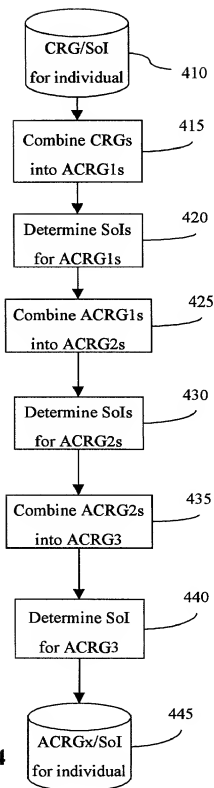


Fig. 4

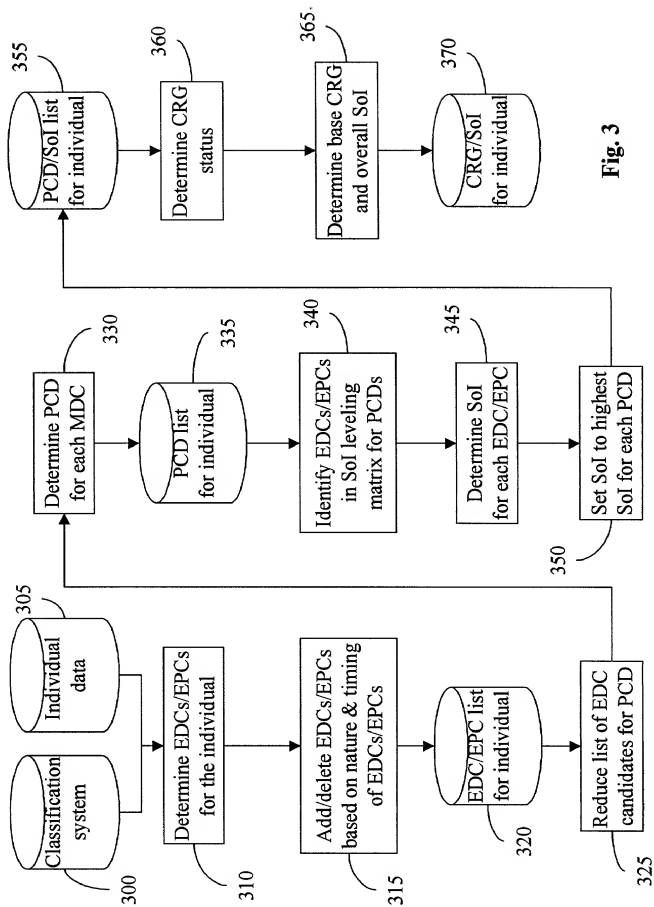


Fig. 3

DECLARATION, POWER OF ATTORNEY, AND PETITION

I, a below named inventor, depose and say that: (1) my residence, citizenship, and mailing address are indicated below; (2) I have reviewed and understand the contents of attached specification, including the claims, as amended by any amendment specifically referred to herein, (3) I believe that the other below named inventors and I are the original, first, and joint inventors or discoverers of the invention or discovery in

Method of Grouping and Analyzing Clinical Risks, and System Thereof

described and claimed therein and for which a patent is sought; and (4) I hereby acknowledge my duty to disclose to the Patent and Trademark Office all information known to me to be material to the patentability as defined in Title 37, Code of Federal Regulations, §1.56.*

I hereby appoint Gregory D. Allen (Reg. No. 35,048), Scott A. Bardell (Reg. No. 39,594), Carolyn A. Bates (Reg. No. 27,853), Stephen W. Bauer (Reg. No. 32,192), Dale A. Bjorkman (Reg. No. 33,084), Jennie G. Boeder (Reg. No. 28,952), William J. Bond (Reg. No. 32,400), Stephen W. Buckingham (Reg. No. 30,035), Paul W. Busse (Reg. No. 32,403), Gerald F. Chernivec (Reg. No. 26,537), James D. Christoff (Reg. No. 31,492), David R. Cleveland (Reg. No. 29,524), Philip Y. Dahl (Reg. No. 36,115), Charles L. Dennis II (Reg. No. 30,555), Janice L. Dowdall (Reg. No. 31,201), Lisa M. Fagan (Reg. No. 40,601), Darla P. Fonseca (Reg. No. 31,783), John A. Fortkort (Reg. No. 38,454), Matthew J. Goggin (Reg. No. 44,125), Melanie G. Gover (Reg. No. 41,793), Gary L. Griswold (Reg. No. 25,396), Doreen S. L. Gwin (Reg. No. 35,580), H. Sanders Gwin (Reg. No. 33,242), Michael A. Hakamaki (Reg. No. 40,011), Karl G. Hanson (Reg. No. 32,900), Néstor F. Ho (Reg. No. 39,460), Jeffrey J. Hohenshell (Reg. No. 34,109), Robert W. Hoke (Reg. No. 29,226), John H. Hornickel (Reg. No. 29,393), MarySusan Howard (Reg. No. 38,729), Stephen C. Jensen (Reg. No. 35,207), Robert H. Jordan (Reg. No. 31,973), Harold C. Knecht III (Reg. No. 35,576), Kent S. Kokko (Reg. No. 33,931), Charles D. Levine (Reg. No. 32,477), Douglas B. Little (Reg. No. 28,439), Eloise J. Maki (Reg. No. 33,418), Lisa M. McGeehan (Reg. No. 41,185), Matthew B. McNutt (Reg. No. 39,766), Michelle M. Michel (Reg. No. 33,968), William D. Miller (Reg. No. 37,988), Peter L. Olson (Reg. No. 35,308), Daniel R. Pastirk (Reg. No. 33,025), David B. Patchett (Reg. No. 39,326), Carolyn V. Peters (Reg. No. 33,271), Scott R. Pribnow (Reg. No. 43,869), Terryl K. Qualey (Reg. No. 25,148), Ted K. Ringsred (Reg. No. 35,658), James A. Rogers (Reg. No. 37,228), Daniel C. Schulte (Reg. No. 40,160), Steven E. Skolnick (Reg. No. 33,789), Robert W. Sprague (Reg. No. 30,497), Brian E. Szymanski (Reg. No. 39,523), James J. Trussell (Reg. No. 37,251), F. Andrew Ubel (Reg. No. 36,704), and Lucy C. Weiss (Reg. No. 32,834), my attorneys and/or agents with full powers (including the powers of appointment, substitution, and revocation) to prosecute this application and any division, continuation, continuation-in-part, reexamination, or reissue thereof, and to transact all business in the Patent and Trademark Office connected therewith; the mailing address and the telephone number of the above-mentioned attorneys and/or agents are

Attention: Charles L. Dennis II
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The undersigned petitioner declares further that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

*Title 37, Code of Federal Regulations, §1.56 is attached.

This form may be executed only when attached to the specification (including claims) as the last page thereof.

0930236-042999

Wherefore, I pray for grant of Letters Patent for the invention or discovery described and claimed in the attached specification and we hereby subscribe our names to the foregoing specification and claims, declaration, power of attorney, and this petition, on the day set forth below.

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